CLAIMS

We claim:

1. A composition for the controlled release of a drug comprising a polyethylene glycol-chitosan conjugate, wherein the polyethylene glycol-chitosan conjugate comprises a chitosan or chitosan derivative moiety and a polyethylene glycol or a polyethylene glycol derivative moiety, and the composition is formulated for delivery to a mucosal membrane.

2. The composition of claim 1, wherein the chitosan or chitosan derivative moiety has a molecular weight of 10 kD to 1000 kD.

3. The composition of claim 1 , wherein the chitosan or chitosan derivative moiety has a molecular weight of 20 kD to 500 kD.

4. The composition of claim 1, wherein the chitosan or chitosan derivative moiety has a molecular weight of 100 kD to 300 kD.

5. The composition of claim 1, wherein the polyethylene glycol-chitosan conjugate is represented by the formula (I):

(I)

wherein C_m is a remainder of a monomeric unit of a chitosan or a chitosan derivative moiety; p is an integer of 50 to 6000;

R^1 is independently selected from a hydrogen atom and , wherein R^2 is selected from a bond and a first divalent organic group; X is selected from an oxygen atom, a sulfur atom, and the group $-NR^3-$, wherein R^3 is selected from a hydrogen atom and a monovalent organic group; and [PEG] is a polyethylene glycol or polyethylene glycol derivative moiety,

provided that 1% to 99% of the groups represented by R^1 is .

6. The composition of claim 5, wherein C_m is the remainder of the monomeric unit of chitosan.

7. The composition of claim 5, wherein p is an integer of 150 to 2,000.

8. The composition of claim 5, wherein [PEG] is $-R^4-(OCH_2CH_2)_n-$, and R^4 is a hydrocarbon group selected from the group consisting of an aliphatic hydrocarbon, an alicyclic hydrocarbon, and an aromatic hydrocarbon, and n is an integer of 10 to 1,000.

9. The composition of claim 8, wherein R^4 is an alkyl group.

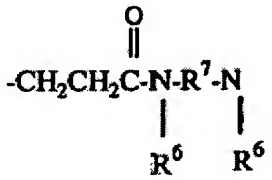
10. The composition of claim 8, wherein R^4 is a methyl group.

11. The composition of claim 5, wherein R^2 is

(II)

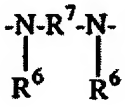
wherein R^5 is a divalent organic group that is bonded to the carbonyl group of R^1.

12. The composition of claim 5, wherein R^2 is



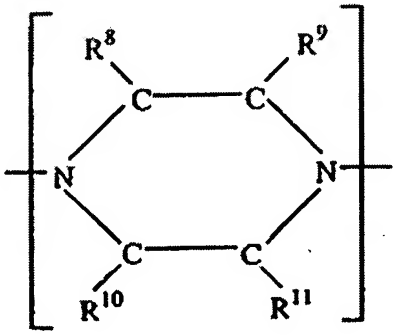
and R^6 is independently selected from a linear or a branched alkyl group having one to four carbon atoms and R^7 is a divalent organic group.

13. The composition of claim 11, wherein R^5 is selected from the group consisting of



(III)

wherein R^6 is independently selected from a linear or a branched alkyl group, and R^7 is a divalent organic group; and



(IV)

wherein each of R^8, R^9, R^{10}, and R^{11} is independently selected from a hydrogen atom and a linear or branched alkyl group having one to three carbon atoms.

14. The composition of claim 1, which has been prepared by compression and is intended for delivery to the gastrointestinal tract.

15. The composition of claim 1, which is in the form of microspheres, microparticles or matrices.

16. The composition of claim 1 for administration to the nasal cavity, the buccal cavity or the vaginal cavity.

17. A method for the preparation of a composition for the controlled release of a drug across a mucosal membrane comprising a polyethylene glycol-chitosan conjugate, the method comprising preparing the polyethylene glycol-chitosan conjugate by bonding the amino function of an activated chitosan species to a polyethylene glycol or polyethylene glycol derivative moiety.

18. The method of claim 17, wherein the activated chitosan species is prepared using bis(acrylamide).